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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,247	02/11/2002	Gary L. Griffiths	018733-1093	9630

22428 7590 09/08/2003

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EXAMINER
HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	10/071,247	GRIFFITHS, GARY L.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence ddress --

THE REPLY FILED 11 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ they raise the issue of new matter (see Note below);
   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____.
3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *None*.

   Claim(s) objected to: *13-15*.

   Claim(s) rejected: *9-12 and 16-20*.

   Claim(s) withdrawn from consideration: *None*.
8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's arguments have been fully considered but not found convincing for the same reasons set forth in Paper No 7. Applicant argues that a skilled artisan readily can generate antibodies to any immunogen and from those antibodies can prepare antibody fragments that are specific to the immunogen. However, there is insufficient guidance as to the binding specificity of the bispecific antibody or the antibody fragment in the claimed ~~method~~ conjugate. Although the F-18 peptide may be used as immunogen to generate antibody that is specific for the F-18 peptide, the binding specificity of the other half of the bispecific antibody is not disclosed, much less using the undisclosed bispecific for any purpose. Even if the bispecific antibody is limited to the F-18 peptide and the double DNA autoantibodies found in SLE, the term "comprising" is open-ended. It expands the F-18 lebeld peptide to include additional amino acid at either or both ends. There is insufficient guidance and working example demonstrating that immunizing an undisclosed F-18 labeled peptide would genereate antibody that is specific for F18 labeled antibody as set forth in claims 13-15. Kuby et al teach that immunizing a peptide comprising a contiguous amino acid sequence of 8 amino acid residues or a protein derived from a full-length polypeptide may result in antibody specificity that differs from antibody specificity directed against the native full-length polypeptide. Colman et al teach that even a single amino acid changes within the interface of an antibody-antigen can raise or lower the affinity of the antibody (See page 33, in particular). Given the indefinite number of undisclosed antibody, F 18 labeled peptide, it is unpredictable which undisclosed antibody and undisclosed F-18 labeled peptide would be useful for a detection method. Since the F-18 labeled peptide is not enabled, it follows that any low molecular weight hapten conjugated to any undisclosed F-18 labeled peptide is not enabled. It also follows that the method of labeling any undisclosed peptide and any metal chelate complex to any undisclosed peptide are not enabled. All rejections remain.

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